REMARKS

Claims 13-17 and 20 are pending in this present application. In the June 8, 2010 Final Office Action, the Examiner:

1. Rejected claims 13-17 and 20 under 35 U.S.C §112, first paragraph, as failing to comply with the written description requirement.

Claims 13-17 and 20 presently stand rejected. Applicant traverses these rejections. Reconsideration of the pending claims is respectfully requested.

I. REJECTIONS UNDER 35 U.S.C. § 112

The Examiner rejected claims 13-17 and 20 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In rejecting claims 13-17 and 20, the Examiner stated:

> The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Any negative limitation or exclusionary proviso must have basis in the original disclosure. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. MPEP 2173.05(i). In this case the language "...the first cannula being empty of any liquid..." and "...the second cannula being empty of any liquid..." and "...the shunt being empty of any liquid...", in combination with the other elements in the claims, in claims 13 and 20 are not disclosed in the original disclosure and thus fails to comply with the written description requirement. It is noted that the specification states that the cannulae are purged to prevent air from entering the blood stream, but fail to state whether the cannulae do or do not contain any liquid. Therefore, since the specification does not recite that the cannulas and/or the shunt contain liquid or do not contain liquid, it is considered new matter (*i.e.* the applicant can not pick and choose which particular limitations to discount without having support for those limitations and it is suggested to only claim what is disclosed-the purging of the cannulae). The use of a negative limitation or exclusionary proviso must have support in the original disclosure. See MPEP 2173.05(i).

Applicants respectfully submit that "...the second cannula being empty of any liquid..." and

"...the shunt being empty of any liquid..." are more than sufficiently supported in the specification.

Paragraph [0025] of the specification states:

> **[0025]** To assemble the shunt 20, the tubing 22 is cut to the appropriate length, and the adapters 24a, 24b are connected to the tubing 22 by inserting a ¼" ID sections 52 into the ends of the tubing. The tubing is then tightly secured to the adapters 24a, 24b by way of plastic cable clamps 64 positioned between the luer-lock flanges. Lastly, the shunt 20 is sterile packaged, *e.g.* in a standard, sealed disposable, easily-opened container such as a pouch, either by itself or with another shunt for biventricular assists. (Because such sterile packaging is well known, it is not shown in the drawings).

The shunt is not described as being filled with <u>any</u> liquid.

Paragraphs **[0030]**-**[0032]** state:

> **[0030]** To use the shunt 20, the patient is prepped and his or her heart is accessed, according to standard medical practices. This may include the IV administration of Heparin at a dose of 10,000 IU.
> **[0031]** Next, the venous cannula 26 (a 20Fr, angled, conventional venous cannula) is conventionally surgically attached to the left atrium 40 (assuming a left ventricular assist), and the aortic cannula 28 (a 22Fr conventional aortic cannula) is conventionally surgically attached to the aorta 44. Both cannulae 26, 28 are purged during the surgical connection process to prevent air from entering the blood stream, if necessary, and both are initially clamped with standard clamps 90.
> **[0032]** Next the vented cannula adapters 24a, 24b are securely attached to the cannulae 26, 28, respectively.

No mention is made in paragraphs **[0030]**-**[0032]** of adding any liquid such as saline or blood from external sources to either the cannula or the shunt. The cannulae are also not attached with any liquid already in them. Clearly, the cannulae are empty during attachment and purged using the patient's own blood in paragraph **[0031]**. When the adapters 24a, 24b are attached to their respective cannulae, the shunt is also attached since the shunt and adapters 24a, 24b are already assembled as described in paragraph **[0025]** clearly forming a closed system with the cannulae and the patient's heart. Paragraph **[0033]** described priming the shunt by a sequence of opening the caps on the adapters and unclamping the cannulae that guide the

patient's blood so as to purge the cannulae and the shunt **without adding any other liquid**.

Applicants respectfully submit that the specification provides a sufficient written description for one of ordinary skill in the art to understand that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 13-17 and 20 therefore comply with 35 U.S.C. § 112, first paragraph, and are in condition for allowance.

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CONCLUSION

Favorable consideration is respectfully requested in view of the foregoing amendments and remarks.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to our Deposit Account No. 50-2542. A copy of this sheet is enclosed.

Respectfully submitted,

Dated: 08/09/2010.

Francisco A. Rubio-Campos, No. 45,358
The Eclipse Group LLP

10605 Balboa Blvd., Suite 300
Granada Hills, CA 91344

(959) 851-5000 ext. 109 Telephone
(818) 332-4205 Fax
frc@eclipsegrp.com

Customer No.: **34408**